01-04-07

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AM-101305

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 10/767,824	Confirmation No.: 5606
Applicant	: Cooperstone et al	
Filed	: January 29, 2004	
Patent No.	: 7,060,709	
Issue Date:	: June 13, 2006	
TC/A.U.	: 1614	
Examiner	: Henley	
Customer No.	: 38199	
Title	: METHOD OF TREATING HEPATIC FIBROSIS	

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
ATTN: Certificate of Correction Branch

Sir:

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 35 USC SECTION 254

The following errors were found in the above-identified patent:

(1) Claim 10, Col. 8, line 64, replace "claim 1," with -- claim 6, -- ;

It is requested that a Certificate of Correction be issued to correct the above error in accordance with the enclosed Form PTO 1050, which is submitted herewith.

Error (1) was changed due to the Examiners Amendment dated January 6, 2006. No fee is due for correction of this error.

Enclosed is a photocopy of the original specification page with the relevant words or phrases highlighted in blue and the corresponding original patent with an error marked in red. Also enclosed is a copy of Page 2 of the Examiners Amendment. These documents will support this error.

The Director of the US Patent and Trademark Office is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing, or during prosecution of this application to Deposit Account No. 08-3040.

Respectfully submitted,
HOWSON & HOWSON LLP
Attorneys for the Applicants

BY _____
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PTO/SB/21 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
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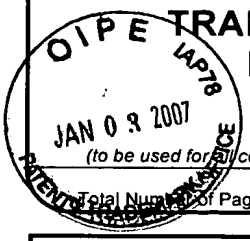


TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/767,824
Filing Date	January 29, 2004
First Named Inventor	Cooperstone et al
Art Unit	1614
Examiner Name	Henley
Total Number of Pages in This Submission: 8	Attorney Docket Number: AM-101305

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  2 pp. Request for Certificate of Correction under 35 USC Section 254
  1 pp. Copy of Original Patent
  1 pp. Copy of Specification Page

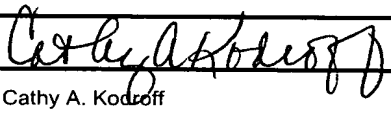
Remarks

2 pp. Copy of Examiners Amendment
1 pp. Form PTO/SB/44

Express Mail No. EO 928 447 892 US

Customer No. 38199

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howson and Howson LLP		
Signature			
Printed name	Cathy A. Kodroff		
Date	January 3, 2007	Reg. No.	33,980

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

ERROR (1)

other antioxidants as part of the antioxidant component of the invention. For example, an acceptable formulation may contain both citric acid and d,l-α-tocopherol. Optimal concentrations for the selected antioxidant(s) can be readily determined by one of skill in the art, based upon the information provided herein.

Advantageously, in certain embodiments of the parenteral formulations useful in the invention, precipitation of CCI-779 upon dilution with aqueous infusion solutions or blood is prevented through the use of a surfactant contained in the diluent solution. The most important component of the diluent is a parenterally acceptable surfactant. One particularly desirable surfactant is polysorbate 20 or polysorbate 80. However, one of skill in the art may readily select other suitable surfactants from among salts of bile acids (taurocholate, glycocholate, cholate, deoxycholate, etc.) which are optionally combined with lecithin. Alternatively, ethoxylated vegetable oils, such as a pegylated castor oil [e.g., such as PEG-35 castor oil which is sold, e.g., under the name Cremophor EL, BASF], vitamin E tocopherol propylene glycol succinate (Vitamin E TGPS), and polyoxyethylene-polyoxypropylene block copolymers can be used in the diluent as a surfactant, as well as other members of the polysorbate family such as polysorbate 20 or 60 Other components of the diluent may include water, ethanol, polyethylene glycol 300, polyethylene 400, polyethylene 600, polyethylene 1000, or blends containing one or more of these polyethylene glycols, propylene glycol and other parenterally acceptable cosolvents or agents to adjust solution osmolarity such as sodium chloride, lactose, mannitol or other parenterally acceptable sugars, polyols and electrolytes. It is expected that the surfactant will comprise 2 to 100% w/v of the diluent solution, 5 to 80% w/v, 10 to 75% w/v, 15 to 60% w/v, and preferably, at least 5% w/v, or at least 10% w/v, of the diluent solution.

A parenteral formulation useful in the invention can be prepared as a single solution, or preferably can be prepared as a cosolvent concentrate containing CCI-779, an alcoholic solvent, and an antioxidant, which is subsequently combined with a diluent that contains a diluent solvent and suitable surfactant. Prior to use, the cosolvent concentrate is mixed with a diluent comprising a diluent solvent, and a surfactant. When CCI-779 is prepared as a cosolvent concentrate according to this invention, the concentrate can contain concentrations of CCI-779 from 0.05 mg/mL, from 2.5 mg/mL, from 5 mg/mL, from 10 mg/mL or from 25 mg/mL up to approximately 50 mg/ml. The concentrate can be mixed with the diluent up to approximately 1 part concentrate to 1 part diluent, to give parenteral formulations having concentrations of CCI-779 from 1 mg/mL, from 5 mg/mL, from 10 mg/mL, from 20 mg/mL, up to approximately 25 mg/ml. For example the concentration of CCI-779 in the parenteral formulation may be from about 2.5 to 10 mg/mL. This invention also covers the use of formulations having lesser concentrations of CCI-779 in the cosolvent concentrate, and formulations in which one part of the concentrate is mixed with greater than 1 part of the diluent, e.g., concentrate: diluent in a ratio of about 1:1.5, 1:2, 1:3, 1:4, 1:5, or 1:9 v/v and so on, to CCI-779 parenteral formulations having a CCI-779 concentration down to the lowest levels of detection.

Typically the antioxidant may comprise from about 0.0005 to 0.5% w/v of the formulation. The surfactant may for example comprise from about 0.5% to about 10% w/v of the formulation. The alcoholic solvent may for example comprise from about 10% to about 90% w/v of the formulation.

The parenteral formulations useful in this invention can be used to produce a dosage form that is suitable for administration by either direct injection or by addition to sterile infusion fluids for intravenous infusion.

For the purposes of this disclosure, transdermal administrations are understood to include all administrations across the surface of the body and the inner linings of bodily passages including epithelial and mucosal tissues. Such administrations may be carried out using the present compounds, or pharmaceutically acceptable salts thereof, in lotions, creams, foams, patches, suspensions, solutions, and suppositories (rectal and vaginal).

Transdermal administration may be accomplished through the use of a transdermal patch containing the active compound and a carrier that is inert to the active compound, is non-toxic to the skin, and allows delivery of the agent for systemic absorption into the blood stream via the skin. The carrier may take any number of forms such as creams and ointments, pastes, gels, and occlusive devices. The creams and ointments may be viscous liquid or semisolid emulsions of either the oil-in-water or water-in-oil type. Pastes comprised of absorptive powders dispersed in petroleum or hydrophilic petroleum containing the active ingredient may also be suitable. A variety of occlusive devices may be used to release the active ingredient into the blood stream such as a semi-permeable membrane covering a reservoir containing the active ingredient with or without a carrier, or a matrix containing the active ingredient. Other occlusive devices are known in the literature.

Suppository formulations may be made from traditional materials, including cocoa butter, with or without the addition of waxes to alter the suppository's melting point, and glycerin. Water soluble suppository bases, such as polyethylene glycols of various molecular weights, may also be used.

The documents identified in the specification are hereby incorporated by reference. A number of variations to the embodiments described herein will be obvious to those of skill in the art and are encompasses by the following claims.

What is claimed is:

1. A method of treating or inhibiting hepatic fibrosis in a mammal in need thereof, which comprises providing to said mammal an effective amount of a CCI-779.

2. The method according to claim 1, wherein CCI-779 is provided to said mammal by oral or intravenous infusion.

3. The method according to claim 1, wherein CCI-779 is provided to said mammal by administration of a prodrug, derivative, pharmaceutical salt or analog of CCI-779 that forms an effective amount of CCI-779 in the body.

4. The method according to claim 1, wherein CCI-779 is administered by direct targeting to the liver.

5. The method according to claim 1, wherein CCI-779 is provided to said mammal by oral dose.

6. A method of treating or inhibiting hepatic cirrhosis in a mammal in need thereof, which comprises providing to said mammal an effective amount of a CCI-779.

7. The method according to claim 6, wherein CCI-779 is provided to said mammal by oral or intravenous infusion.

8. The method according to claim 6, wherein CCI-779 is provided to said mammal by administration of a prodrug, derivative, pharmaceutical salt or analog of CCI-779 that forms an effective amount of CCI-779 in the body.

9. The method according to claim 6, wherein CCI-779 is administered by direct targeting to the liver.

10. The method according to claim 1, wherein CCI-779 is provided to said mammal by oral dose.

* * * * *

error (1)

10. The method according to claim 1, wherein CCI-779 is provided to said mammal by oral dose.

EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Cathy Kodroff on January 26, 2006.

The application has been amended as follows:

In the Claims:

In claims 3 and 8, line 1, "wherein CCI-779 provided to said" has been changed to read ---wherein CCI-779 is provided to said---; and

In claim 10, line 1, "claim 1" has been changed to read ---claim ~~1~~ 6---.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	10/767,824	COOPERSTONE ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

All Participants:

(1) *Raymond J. Henley III*.

(2) *Cathy A. Kodroff*.

Status of Application: *Pending*

(3) _____.

(4) _____.

Date of Interview: *26 January 2006*

Time: *PM (E.S.T.)*

Type of Interview:
☒ Telephonic
☐ Video Conference
☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☒ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:
N/A

Claims discussed:
3, 8 and 10

Prior art documents discussed:
None

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
Authorization given to make Examiner's Amendment, said amendment correcting minor informalities in the claims.

Part III.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.
☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

(Examiner/~~SPE Signature~~)

(~~Applicant/Applicant's~~ Representative Signature ~~– if appropriate~~)

PTO/SB/44 (04-05)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 7,060,709

APPLICATION NO. : 10/767,824

ISSUE DATE : June 13, 2006

INVENTOR(S) : Cooperstone et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

(1) Claim 10, Col. 8, line 64, replace "claim 1," with -- claim 6, -- ;

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